

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

PRESIDENT AND FELLOWS OF
HARVARD COLLEGE,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:25-cv-11048-ADB

Leave to File Granted June 6, 2025

**MEMORANDUM OF *AMICUS CURIAE* CONFERENCE OF BOSTON TEACHING
HOSPITALS, INC. IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY
JUDGMENT**

Non-party the Conference of Boston Teaching Hospitals, Inc. (“COBTH”) respectfully submits this Memorandum as *Amicus Curiae* in support of Plaintiff’s Motion for Summary Judgment.

INTEREST OF *AMICUS CURIAE*

COBTH is a non-profit organization comprised of twelve Boston-area teaching hospitals (the “Hospitals”)¹ dedicated to supporting its members’ missions of providing the highest-quality patient care, discovering and advancing new treatments and cures to life-threatening diseases, and training the next generation of researchers, physicians, and other health care professionals. Collectively, the Hospitals have revolutionized treatment for diseases ranging from cancer to Alzheimer’s. COBTH plays a vital role in promoting the Hospitals’ medical breakthroughs and clinical research programs.

The Hospitals are each a party to agreements with one of the Boston-area medical schools: Harvard Medical School, Tufts University School of Medicine, Boston University Chobanian & Avedisian School of Medicine, or UMass Chan Medical School. Neither COBTH nor any of the Hospitals are part of Harvard or any university. The Hospitals have patients residing around the country, run clinical trials in which residents of a majority of U.S. states participate, and partner in clinical relationships from Maine to Ohio. The Hospitals and the respective medical schools are entirely separate entities with independent governance structures, boards, and management teams. However, through critical collaborations with the medical schools, the Hospitals have advanced medical science and improved the lives of countless

¹ The members of COBTH are Beth Israel Deaconess Medical Center, Lahey Hospital & Medical Center, Boston Children’s Hospital, Boston Medical Center, Boston Medical Center – Brighton, Brigham and Women’s Hospital, Mass General Brigham, Mass Eye and Ear, Massachusetts General Hospital, Cambridge Health Alliance, Dana-Farber Cancer Institute, and Tufts Medical Center.

patients across the country. Research at the Hospitals also includes relationships and clinical arrangements with some of the nation's most innovative life sciences companies, which employ hundreds of thousands of Americans. These businesses help make the U.S. the global leader in biopharmaceutical and clinical trial development. These collaborations, and the medical breakthroughs they have supported, are critical to the health of hundreds of thousands of Americans and are now in jeopardy. The work at the Universities and medical schools often feeds the translational research done at the Hospitals, which is funded directly to the Hospitals independent from, and from sources other than, Harvard.

Over the past several weeks, the government has terminated about \$2.4 billion dollars in federal grants to Harvard University.² These grant terminations will have the consequence of threatening the Hospitals' work to continually advance medical science. COBTH is deeply concerned about the impact of the abrupt funding terminations at Harvard on its members' critical work. This Memorandum offers the Court first-hand experience regarding their wide-ranging effects. The funding cuts have already affected important scientific research projects at Harvard, and the termination of federal funding to Harvard presents obvious harm to ongoing research and the education of future scientists and clinicians. But less apparent downstream harms caused by these funding cuts will extend beyond the walls of the University or its Medical School.

The funding cuts will have the unintended, yet real, consequence of damaging the foundation upon which the Hospitals develop medical breakthroughs for their patients. Basic science research—often conducted at universities like Harvard—enables hospitals to do clinical research and develop breakthrough treatments or cures for disease. The Hospitals expand on the

² See Declaration of John Shaw (Dkt. # 72) ¶ 15.

insights derived from the basic science research to launch clinical trials, and ultimately, treat and cure patients. The termination of Harvard’s federal research grants threatens to stunt future discoveries and medical advances.

Further, funding through universities in the form of sub-awards supports important clinical research at the Hospitals. Whether through collaborations or sub-grants, federal funding to universities, including Harvard, indirectly supports the Hospital’s research. COBTH asks the Court to enter summary judgment to the Plaintiff to prevent these collateral consequences of the funding cuts at Harvard.

ARGUMENT

The funding termination should be enjoined because, among other reasons, the government failed to consider “serious reliance interests.” *Dep’t of Homeland Sec. v. Regents of Univ. of Ca.*, 591 U.S. 1, 30 (2020); *Woonasquatucket River Watershed Council v. U.S. Dep’t of Agriculture*, 2025 WL 1116157, at *19 (D.R.I. Apr. 15, 2025) (enjoining funding freeze because the government’s “failure to consider reliance interests led to an arbitrary and capricious action.”). Here, the government’s funding cuts to Harvard threaten the Hospitals’ vital work to advance new treatments and cures for their patients for at least two reasons. First, the Hospitals’ clinical advancements often build upon federally funded basic science research at universities, which promotes their success. Second, federal funding through universities indirectly supports important clinical research at the Hospitals. Terminating Harvard grants will require the Hospitals to end research programs or shift funding from other areas to the detriment of other important parts of the Hospitals’ missions. The government’s disregard of these reliance interests renders the funding cuts arbitrary and capricious. For the same reasons, the balance of equities

and public interest strongly weigh in favor of a permanent injunction. *See, e.g., Ass’n Am. Univs. v. Dep’t of Energy*, 2025 WL 1414135, at *20 (D. Mass. May 15, 2025) (Burroughs, J.).

I. The Discovery and Advancement of New Treatments and Cures at the COBTH Hospitals Regularly Depend on Federally Funded Basic Science Research at Universities.

The Hospitals are part of a world-class national innovation ecosystem that has led to the development in the U.S. of dozens of life-saving treatments and cures for diseases. Along with the discoveries and advances at the Hospitals, the ecosystem includes basic science research at universities funded by the National Institutes of Health (“NIH”) and life sciences companies that bring new therapeutics to market. Each part of this ecosystem is critical to the continued development of new life-saving treatments and cures. While the Hospitals are active in dozens of clinical trials, the NIH funding of basic science research at medical schools and schools of public health across the country is critical to the Hospitals’ development of new medical advances. That innovation ecosystem was built on decades of federally funded basic science research. Indeed, nearly every FDA-approved drug developed in recent years was based, at least in part, on NIH-funded basic research.³ Terminating that research funding to Harvard will fracture this carefully curated innovative ecosystem, threatening future medical and scientific breakthroughs.

Without basic scientific research at universities, there will be fewer scientific discoveries. With fewer scientific discoveries, there will be fewer life-saving medical treatments and cures for disease. There are many examples of how this ecosystem—including basic science research

³ Ekaterina Galkina Cleary et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs. the Pharmaceutical Industry, 2010-2019*, JAMA Health Forum (Apr. 28, 2023), <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378> (“[f]unding from the NIH has contributed to 354 of 356 drugs (99.4%) approved from 2010 to 2019 . . .”).

at medical schools—has led to life-saving medical-breakthroughs at the Hospitals. Here are a few.

In 2019, scientists at Harvard Medical School discovered that a specific protein in the inner ear of mice plays an important role in hearing.⁴ A year later, a 10-year-old girl with hearing loss sought treatment at Boston Children’s Hospital. Uncertain of the cause, Boston Children’s enrolled the young girl in a clinical trial that screened for genetic variants.⁵ The screening found a genetic error in the same protein the Harvard scientists had discovered was involved in mice hearing.⁶ This discovery opened a path to potential treatment using gene therapy, similar to work at Boston Children’s to treat hearing loss caused by defects in other genes.

To take another example, earlier this year, surgeons at Massachusetts General Hospital (“MGH”) performed their second successful transplant of a genetically edited pig kidney into a living patient, a 66-year-old New Hampshire man.⁷ The patient had end-stage kidney disease, but faced a potential wait of five to ten years for a human kidney transplant. Only one week after the successful transplant, the patient left the hospital and was off dialysis for the first time in two years. This pioneering treatment has enormous potential for the more than 500,000 patients on dialysis, and thousands waiting for a kidney transplant.

⁴ See Xudong Wu et al., *PKHD1L1 Is A Coat Protein of Hair-Cell Stereocillia And is Required in Normal Hearing*, 10 Nat. Commun. 3801 (Aug. 23 2019), <https://www.nature.com/articles/s41467-019-11712-w>.

⁵ Harvard Otolaryngology, *Establishing a Nonsyndromic Hearing Loss Gene* (Spring 2024), https://issuu.com/hmsotolaryngology/docs/harvard-otolary-spring-2024-v12-_hires_?fr=xKAE9_zU1NQ.

⁶ See *id.*

⁷ Press Release, *Massachusetts General Hospital Performs Second Groundbreaking Xenotransplant of Genetically-Edited Pig Kidney Into Living Recipient* (Feb. 7, 2025), <https://www.massgeneral.org/news/press-release/mgh-performs-second-xenotransplant-of-genetically-edited-pig-kidney-into-living-recipient>.

The transplant of a genetically edited pig kidney was only possible because of the innovation ecosystem, which built on decades of research, including federally funded scientific research at universities, in this case the University of California – Berkeley. The kidney used in the transplant in Boston was genetically edited by a biotechnology company in Cambridge using CRISPR-Cas9 technology to remove harmful pig genes and add certain human genes. CRISPR-Cas9 technology acts like “genetic scissors,” allowing scientists to modify the genes.⁸ NIH and other federal agencies funded much of the work that led to the discovery of CRISPR and development of the CRISPR-Cas9 technology at UC-Berkeley.⁹ The federal funding of basic science in universities was critical to this scientific breakthrough.

CRISPR technology—and its discovery in NIH-funded basic science research at UC-Berkeley—is the foundation for other life-saving medical breakthroughs. Researchers at the Dana-Farber Cancer Institute have created a CRISPR-based rapid molecular diagnostic for two forms of leukemia that are driven by mutations that involve gene fusions.¹⁰ This new diagnostic would not be available without federal funding of basic science at universities.

There are other examples of the importance of university-based basic science research outside of gene editing technology. Pediatric cancer researchers at the Dana-Farber/Boston Children’s Cancer and Blood Disorder Center found that the medication avapritinib may be effective in treating a type of aggressive brain cancer in children called pediatric high-grade

⁸ Press Release, *The Royal Swedish Academy of Sciences Nobel Prize in Chemistry 2020* (Oct. 7, 2020), <https://www.nobelprize.org/prizes/chemistry/2020/press-release/>.

⁹ David Fajardo-Ortiz et al., *Funding CRISPR: Understanding the role of government and philanthropic institutions supporting academic research within the CRISPR innovation system*, 3 Quantitative Science Studies 443 (June 22, 2022), <https://direct.mit.edu/qss/article/3/2/443/110371/Funding-CRISPR-Understanding-the-role-of>.

¹⁰ News Release, *Dana-Farber Cancer Institute, Rapid Blood Cancer Diagnostic Could Speed Decisions and Save Lives* (Oct. 9, 2024), <https://www.dana-farber.org/newsroom/news-releases/2024/rapid-blood-cancer-diagnostic-could-speed-decisions-and-save-lives>.

glioma.¹¹ Children with this type of cancer have a poor prognosis, so the potential for a new treatment option is significant.¹² Dana-Farber/Boston Children’s discovered the potential benefits of the medicine in a study of the potential role of a specific protein receptor on the surface of human cells.¹³ The promising finding followed years of earlier research, including NIH-funded research at the University of Texas, into the same protein.¹⁴

At Beth Israel Deaconess Medical Center’s (“BIDMC”) Complex Hypertension Clinic, physician-scientists are part of a national clinical study pioneering a treatment for patients with high blood pressure.¹⁵ The new treatment, renal denervation, involves a minimally invasive procedure to calm excessively active nerves connected to kidneys that may contribute to high blood pressure. This potential new treatment builds on decades of NIH-funded research into connections between kidney function and high blood pressure, including work done at a university.¹⁶

These examples—and many others like them—demonstrate the critical role of federal funding for basic science at universities in providing the foundation for new treatments and cures being pioneered at the Hospitals. Threats to the basic research funding at Harvard and other

¹¹ Lisa Mayr et al., *Effective Targeting of PDGFRA-altered high-grade glioma with avapritinib*, 43 *Cancer Cell* 740-56 (Apr. 14, 2025), [https://www.cell.com/cancer-cell/pdf/S1535-6108\(25\)00070-4.pdf](https://www.cell.com/cancer-cell/pdf/S1535-6108(25)00070-4.pdf).

¹² *Id.*

¹³ *Id.*

¹⁴ See, e.g., Carman K M Ip et al., *Neomorphic PDGFRA Extracellular Domain Driver Mutations Are Resistant to PDGFRA Targeted Therapies*, 9 *Nat. Commun.* 4583 (Nov. 2018), <https://pmc.ncbi.nlm.nih.gov/articles/PMC6214970/>.

¹⁵ Beth Israel Deaconess, *Complex Hypertension Clinic*, <https://www.bidmc.org/centers-and-departments/cardiovascular-institute/cardiovascular-medicine/our-services/outpatient-cardiovascular-clinic/complex-hypertension-clinic> (last visited June 6, 2025); NIH, *SPYRAL AFFIRM Global Study of RDN with Symplicity Spyral RDN System with Subjects with Uncontrolled HTN*, <https://clinicaltrials.gov/study/NCT05198674>.

¹⁶ NIH RePORTER, *Aging and hypertension: Integrated renal and sympathetic control of blood pressure*, <https://reporter.nih.gov/project-details/9751048> (last visited June 1, 2025).

universities threaten the continued progress of advances in health care for patients here and across the country.

II. Federal Funding Through Universities Supports Important Clinical Research at the Hospitals.

Through collaborations and subgrants, federal funding to universities supports important clinical research at the Hospitals. Harvard disperses federally funded clinical and translational research grants among various institutions, including the Hospitals.

One prominent example of Harvard's research support is Harvard Catalyst, which has been funded in part by NIH grants to the university. Harvard Catalyst coordinates and supports clinical and translational research among the Hospitals, offering programs for researchers relating to pilot funding, biostatics, regulatory and ethical compliance, and education and training.¹⁷ Harvard Catalyst helps coordinate multisite studies and provides essential guidance and support to the Hospitals' investigators throughout the clinical research process.¹⁸

Through Harvard Catalyst, BIDMC provides laboratory space to more than thirty researchers, and other support across all disease areas, including Huntington's disease, Alzheimer's disease, and kidney disease. In fiscal year 2024, Harvard Catalyst supported 76 principal investigators at BIDMC, working on 152 clinical research projects, who attended to more than 4,500 study visits. Many of the other Hospitals similarly rely on Harvard Catalyst to support their clinic research programs. The funding cuts to Harvard threaten access to this key research infrastructure at the Hospitals.

¹⁷ Harvard Catalyst, *About*, <https://catalyst.harvard.edu/about/> (last visited June 6, 2025).

¹⁸ Harvard Catalyst, *Connector*, <https://catalyst.harvard.edu/connector/> (last visited June 6, 2025).

Harvard Catalyst's Smart IRB, also funded by NIH, aims to quickly and efficiently ensure proper protections for human participants in large clinical trials.¹⁹ To make sure human research participants are protected, traditional Institutional Review Boards take months of due diligence.²⁰ Smart IRB reduced the time and expense to get large clinical studies running down to as few as 20 minutes.²¹ Without Smart IRB, the launch of new clinical trials may be delayed and much more expensive.

Another example of research at risk is the Nurses' Health Study, one of the largest studies into the causes of chronic disease in women over nearly fifty years. The study is a collaboration between Harvard Medical School, Harvard T.H. Chan School of Public Health, and The Brigham and Women's Hospital ("BWH"), and has continuously received NIH funding since 1976.²²

The current iteration of the study continues the collaboration between Harvard and BWH and examines how dietary patterns, lifestyle, environment, and nursing occupational exposures impact men's and women's health, among other issues.²³

Thousands of nurses across the country have participated in the study's decades of research. Thanks to these participants, investigators working on the study have helped shape public health policy and national dietary guidelines.²⁴ For example, the Nurses' Health Study

¹⁹ Harvard Catalyst, *Medical Researchers Baffled by Trump Administration's Stop Work Order for Clinical Trial System: 'A Giant Step Backwards'*, <https://catalyst.harvard.edu/news/article/medical-researchers-baffled-by-trump-administrations-stop-work-order-for-clinical-trial-system-a-giant-step-backwards/> (May 12, 2025).

²⁰ *Id.*

²¹ *Id.*

²² Nurses' Health Study, *History*, <https://nurseshealthstudy.org/about-nhs/history> (last visited June 6, 2025).

²³ *Id.*

²⁴ Nurses' Health Study, *Key Contributions to Scientific Knowledge*, <https://nurseshealthstudy.org/about-nhs/key-contributions-scientific-knowledge> (last visited June 6, 2025).

uncovered links between smoking and cardiovascular disease, and postmenopausal obesity and breast cancer.²⁵ The Study's observations into associations between circulating sex hormones and postmenopausal risk, and Vitamin D levels with colon polyps and colon cancer, have led to new methods of disease treatment and prevention.²⁶ These discoveries are important to the area of disease prevention and would not have been possible without federal funding. The funding cuts to Harvard put future progress at serious risk.

CONCLUSION

Hospitals across the country, like the members of COBTH, conduct research that has kept the United States at the forefront of medical science and improved the lives of countless patients. Federal funding to universities, like Harvard, indirectly supports the Hospitals to continue their lifesaving work. For the reasons above and in Plaintiff's Motion for Judgment, the funding cuts are arbitrary and capricious, and the balance of equities and public interest weigh in favor of enjoining them. COBTH respectfully requests the Court grant Plaintiff's Motion for Summary Judgment.

²⁵ *Id.*

²⁶ *Id.*

June 9, 2025

Respectfully submitted,

/s/ Eric M. Gold

Martin F. Murphy, BBO # 363250

Eric M. Gold, BBO #660393

Max A. Jacobs, BBO # 707327

MANATT, PHELPS & PHILLIPS, LLP

1 Beacon Street, Suite 28-2000

Boston, MA 02108

Tel: 617-646-1400

MFMurphy@manatt.com

EGold@manatt.com

MJacobs@manatt.com

Counsel for

Conference of Boston Teaching Hospitals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that, on June 9, 2025, I caused a true and correct copy of the foregoing to be filed via the Court's ECF system, which will send notice to all counsel of record.

/s/ Eric M. Gold

Eric M. Gold